

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT FOR DATA SHARING

This Agreement is entered into under the authority of the Technology Transfer Act of 1986, as amended and the Health Insurance Portability and Accountability Act of 1996. The parties of this Agreement are: **U.S. Army Institute of Surgical Research** (USAISR), Fort Sam Houston, Texas 78234-6315 (Provider) and

(Recipient).

With respect to Provider furnishing research data and/or information relating to them, the parties agree as follows:

1. Recipient agrees that the Data and/or Information will be used for research purposes only. The data and/or information shall not be sold, offered for sale, used for commercial purposes, or be furnished to any other party without advance written approval from the , Commander, USAISR, and any use or furnishing of Data and/or Information shall be subject to the restrictions and obligations imposed by this Agreement. This Data/Information will be shared only in accordance with an appropriate Institutional Review Board (IRB) approved protocol or a preparatory request for research data, to include those countries that abide by the International Conference on Harmonisation (ICH). The parties mutually agree that USAISR is the repository and gatekeeper of the Data and/or Information and that the recipient does not obtain any right, title, or financial interest in any of the Data and/or Information to which USAISR grants access.
2. The purpose of this Agreement is the provision of the Data and/or Information and Information; no further collaboration is contemplated. Any intellectual property rights to the Data and/or Information in existence prior to this Agreement, or potential rights, such as issued patents, patent applications or invention disclosures are retained by the Provider. Any invention patentable under U.S. patent law which is conceived or first reduced to practice under the Agreement shall be owned by the party entitled to ownership under U.S. patent law. The Provider agrees to grant an exclusive license to any invention arising under this Agreement to which it has ownership to the Provider in accordance with Title 15 U.S. Code Section 3710a, and pertinent federal regulations, on terms negotiated in good faith. Any invention arising under this Agreement is subject to the retention by the U.S. Government of a nonexclusive, irrevocable, paid-up license to practice, or have practiced, the invention throughout the world by or on behalf of the U.S. Government.
3. The parties shall maintain in confidence all Information relating to these Data and/or Information and shall not disclose Information to others without specific written permission, in advance, unless required to by law. The Recipient will demonstrate compliance with all required Human Subject Protection Training and Principles. In any event, the parties agree to promptly communicate any third party request for information.

4. When the Data and/or Information are no longer being used for research purposes, in accordance with this Agreement, all Data and/or Information will be destroyed or unless otherwise directed, in writing, by USAISR.
5. Recipient agrees to report in a timely manner the results of any research with the Data and/or Information and its products to the Provider. If requested, Recipient agrees to provide all data supporting research results to the Provider.
6. The Data and/or Information are provided as a service to the research community and other investigators may request the same data sets from the USAISR repository. The Data and/or Information are provided without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. No indemnification for any damages is intended or provided under this Agreement. Each party shall be responsible for any damages it incurs as a result of its activities under this Agreement.
7. In all oral or written publications concerning the research done or to be done by Recipient with the provided Data and/or Information, Provider's contribution is to be expressly noted, by either acknowledgement or co-authorship, as appropriate, based on level of collaboration. For the purpose of restricting any disclosure of Provider's confidential information, Recipient will send all proposed publications to Provider for review. All publications based on this data sharing agreement will also be reviewed for compliance with the guidelines for the Release of Actionable Medical Information, (OTSG MEDCOM Policy Memo # 05-018, available on ISR website). Provider will return comments or suggested revisions to the proposed publications to Recipient within a maximum of thirty (30) calendar days of their receipt by Provider. The results of the research will be made easily accessible to non-participating researchers and the public.
8. If the parties decide to collaborate on research using the Data and/or Information for non-Federal organizations, the appropriate avenue for that purpose is through a Cooperative Research and Development Agreement (CRADA). For federal organizations seeking collaboration of the ISR on research projects, the appropriate avenue for that purpose is the Memorandum of Agreement (MOA) or the Memorandum of Understanding (MOU), unless there is a preexisting research agreement between the organizations.
9. The non-Federal party to this Agreement agrees to make no claim or inference regarding this Agreement, the Data and/or Information or its products, which implies governmental endorsement or recommendation.
10. This Agreement shall be construed in accordance with the laws of the United States Government.
11. The obligation of the parties to transfer technology to one or more other parties, provide technical information and reports to one or more other parties, and otherwise perform under this Agreement are contingent upon compliance with applicable United States export control laws and regulations. The transfer of certain technical data and

commodities may require a license from a cognizant agency of the United States Government or written assurances by the Parties that the Parties shall not export technical data, computer software, or certain commodities to specified foreign countries without prior approval of an appropriate agency of the United States Government. The Parties do not, alone or collectively, represent that a license shall not be required, nor that, if required, it shall be issued.

12. The Provider may terminate this Agreement unilaterally at any time by giving the Recipient written notice.

This Agreement is effective as of the last date of signature of all authorized officials of the parties and shall be effective for three (3) years.

For (Recipient):

Name of Investigator/Requestor _____ Date _____

Position/Title of Investigator _____

E-mail Address _____

Name of Institution Official _____ Date _____

Position/Title of Institution Official _____

Official Organization Name _____

Address _____

Voice Phone # _____ FAX # _____

E-mail Address _____

For the U.S. Army Institute of Surgical Research

JOHN B. HOLCOMB, MD
Colonel, Medical Corps
Commander

Date